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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,313	06/30/2006	John Eldridge	AM101319	8349

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EXAMINER	
HIRIYANNA, KELAGINAMANE T	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,313	ELDRIDGE ET AL.	
	Examiner	Art Unit	
	KELAGINAMANE T. HIRIYANNA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *1-34 and 40-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/03/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on *04/17/2009* in response to office action mailed on 03/27/2009 has been acknowledged.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is ***571-273-8300.***

Restriction of invention

Applicant's election without traverse of the restriction requirement in the reply filed on August 22, 2008 is acknowledged. Applicant elects with traverse the invention Group II (Claims 35-39) for further prosecution on merits. Applicant's election of species is noted.

Claims 35-39 are pending and presently under examination.

Claims 1-34 and 40-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected claims, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on *04/17/2009.*

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 35, 37 and 38 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

Claims 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to "an immunogenic composition", but the composition comprises "(a) a first composition" and "(b) at least one recombinant …". What is the metes and bounds? One composition, or two?

Claims 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim 37 is drawn to “VSV is non-replicating”. Does a VSV that is fully competent to replicate anticipate this claim at those times it is not replicating? Or is it limited to replication-incompetent VSV?

Claims 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim 38 is drawn to "A composition" of Claim 35, but requires a second composition. Are two separate compositions being claimed? Applicant is required to clarify.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The Claims 38 & 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cytokine that can induce an antigen specific immune response to antigen is not enabled for any cytokine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At issue, under the enablement requirement of 35 U.S.C. 112, first paragraph is whether, given the Wands-factors, the experimentation was undue or unreasonable under the circumstances. “Experimentation must not require ingenuity beyond that to be expected of one of ordinary skill in the art." See Fields v. Conover, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970). Since the specification fails to disclose how any and/or all cytokines can induce antigen specific response. Art at the time of invention and still unpredictable regarding using or administering all the known cytokines for the purposes enhancing or inducing a immune response in animals. For example Akdis et al (2001, Immunology 103:131-136 teaches that there are several immune suppressor cytokines

wherein Akdis further provides an example immune suppressing cytokine namely interleukin-10 (IL-10) which plays a key role in tolerizing exogenous antigens (entire article; abstract, p.131, col.1). At issue, under the enablement requirement of 35 U.S.C. 1 12, first paragraph is whether, given the Wands-factors, the experimentation was undue or unreasonable under the circumstances. “Experimentation must not require ingenuity beyond that to be expected of one of ordinary skill in the art." See Fields v. Conover, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-37 are rejected under 102(b) as being anticipated by Rose et al (WO 96/34625; art of record).

The above claims are drawn to an immunogenic composition to induce antigenic response in a mammalian subject wherein the composition comprises a first composition comprising a DNA plasmid comprising a DNA sequence encoding an antigen under the control of regulatory sequences and at least one recombinant stomatitis virus (VSV) comprising a nucleic acid sequence encoding said antigen directed by said recombinant VSV,

Regarding claims 35-39 Rose (WO 96/34625). teaches an immunogenic composition comprising a plasmid DNA expression vector with foreign DNA encoding antigens and NPL proteins and a recombinant VSV comprising the cloned sequence encoding N, P, L proteins and foreign antigen are introduced into same cells to result in assembly of recombinant immunogenic VSV (see for example p.40, lines 4-37 bridging

p.41; p.42, lines 30-37 bridging p.43; p.38; p123-132). Thus (WO 96/34625) clearly anticipates the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35-37 are rejected under 35 USC 103 (a) as being unpatentable over Hag;und et al (2002, J. Virol. 76:7507-7517) in view of Ramshaw et al (2000, Trends Immunology Today 21:164-165; art of record).

The above claims are drawn to an immunogenic composition to induce antigenic response in a mammalian subject wherein the composition comprises a first composition comprising a DNA plasmid comprising a DNA sequence encoding an antigen under the control of regulatory sequences and at least one recombinant stomatitis virus (VSV) comprising a nucleic acid sequence encoding said antigen directed by said recombinant VSV,

Regarding claims 35-37 Hagllund teaches prime boost regimens comprising multiple vectors that includes VSV for inducing efficient antigenic response in mammals (entire article; abstract). Haglund teaches that prior art routinely uses prime-boost regimen using DNA vaccine vectors (plasmid expression vectors as vaccine) and viral vaccine vectors and Hagllund in particular uses VSV vector along with a heterologous vector (eg. Vaccinia virus vector) coding the same antigen. Haglund however, does not use a plasmid vector in his prime boost composition comprising VSV

Ramshaw teaches the prime-boost strategy as an exiting prospect for improved vaccination (entire article; abstract). Ramsha's prime boost vaccine i particular comprises DNA vaccines (plasmid vectors with antigen) and attenuated poxvirus vectors encoding similar heterololous antigens (entire article)

Thus it would have been obvious for one of ordinary skill in the art to incorporate a plasmid vaccine vector encoding the antigen in the regimen of Hauglund as taught by Ramshaw and other prior art and the use said composition for prime-boost strategy for

inducing an antigen specific immune response in a mammal.. One of ordinary skill in the art would have been motivated to make and use said prime-boost strategy of immunizing with a VSV vector coding for same antigen as the first plasmid vaccine vector as it provides improved vaccination. One of ordinary skill in the art would have reasonable expectation of success making using said compositions because of the prior art teaches improved vaccination with a composition of DNA vaccine vector and a viral vector comprising the same antigens and prior art further clearly teaches prime boost using VSV.. Thus, the claimed invention was *prima facie* obvious.

Claims 38-39 are rejected under 35 USC 103 (a) as being unpatentable over Hag;und et al (2002, J. Virol. 76:7507-7517) in view of Ramshaw et al (2000, Trends Immunology Today 21:164-165).applied to claims 35-37 as above and further in view of Gerhardi et al (2001, Histol. Histopathol. 16:655-667)

The above claims are drawn to an immunogenic composition to induce antigenic response in a mammalian subject wherein the composition comprises a first composition comprising a DNA plasmid comprising a DNA sequence encoding an antigen under the control of regulatory sequences and at least one recombinant stomatitis virus (VSV) comprising a nucleic acid sequence encoding said antigen directed by said recombinant VSV,

Regarding claims 35-37 Hagllund and Ramshaw teach above the prime-boost strategy as an exiting prospect for improved vaccination (entire article; abstract wherein the prime boost vaccines comprises DNA vaccines (plasmid vectors with antigen) and a viral vectors encoding similar or same heterololous antigens. Hagllund and Ramshaw however, do not teach using vaccine further comprising a cytokine composition.

Gehrardi teaches new generation of vaccines with cytokines as an adjuvant (IL-12 or IL-12 encoding sequences) enhance cellular immune reponses to pathogens during prime-booster vaccination regimens (abstract).

Thus it would have been obvious for one of ordinary skill in the art to incorporate a cytokine encoding and expressing sequences in the prime-boost vaccine regimen of Hauglund and Ramshaw and enhance antigen specific immune response as taught by

Gerhardi. One of ordinary skill in the art would have been motivated to make and use said prime-boost strategy of immunizing with a VSV and plasmid vectors further encoding a cytokine in order to achieve increased immune response. One of ordinary skill in the art would have reasonable expectation of success making using said compositions because of the prior art teaches improved vaccination with a composition of DNA vaccine vector and a viral vector comprising the same antigens and prior art further clearly teaches prime boost using a VSV vector and still further teaches increasing immune response to such vaccine in presence of a cytokine.. Thus, the claimed invention was *prima facie* obvious.

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.,* whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.,* may be reached at **(571) 272-0739.** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/Robert M Kelly/

Primary Examiner, Art Unit 1633